REMARKS

This is in response to the Official Action mailed July 7, 2006. Claims 1-20 are pending, with claim 11 being rewritten as an independent claim and claims 13-20 being newly presented. Claims 1-6, 8-10, and 12[1] were rejected as anticipated by Brimhall (U.S. Patent No. 6,004,294). Applicants disagree.

The present application is directed to an intravenous catheter introducer assembly which, in addition to a catheter assembly and a needle assembly, has a protector with a hollow member, and structure to interact with a groove of the needle to hold the needle tip inside the protector after withdrawal of the needle from the catheter. In some embodiments, the protector is a tube, and the interacting structure is defined by one or more inwardly directed flanges formed by deflecting a portion of the protector itself (referred to herein as an "integral flange" for sake of convenience and not by way of limitation in this or any related case). In one embodiment, namely Figure 9, the interacting structure is defined by a resilient leg(s) of a clip mounted to the protector.

This application is a divisional of a parent case, now U.S. Patent No. 6,663,592. As originally filed, the parent case included claim 1 that called for an intravenous catheter introducer assembly including a needle assembly, protector and catheter assembly like current claim 1, but instead of specifically reciting either the integral flange or the clip with a resilient leg, merely recited an "inwardly directed flange" so as to attempt to broadly cover all of the embodiments disclosed, including Figure 9 which showed a clip 270. In the parent case, Examiner asserted a five-way species election requirement between various figures, with one of the five patentably distinct species being specifically identified as the clip shown in Figure 9 (Official Action mailed April 1, 2003). Applicants attempted to traverse the rejection (Response to Restriction Requirement dated June 18, 2003), but were rebuffed. In particular, Examiner took the clear position that claim 1, calling for the "inwardly directed flange," was not generic and specifically did not include a clip and resilient leg as shown in the species of Figure 9. Examiner thus held:

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[1] Applicants gratefully acknowledge Examiner's allowance of claim 7 and the indication of allowable subject matter of claim 11. Claim 11 has been rewritten in independent form and is thus submitted to now be in condition for allowance as well.

> Species III, as drawn to Figure 9, requires a clip 270, which cannot be interpreted as an inwardly disposed resilient flange as provided in the other Figures. It is believed that claim 1 is generic to only Species I, II, IV and V.

Official Action mailed July 14, 2003, at 2. In other words, an invention directed to or disclosing a protector with a hollow member and an inwardly directed flange is, by the Office's own rulings, patentably distinct from a protector with a clip and resilient leg. The claims of the present divisional are directed to the clip/resilient leg species of Figure 9.

For sake of argument, it will be assumed that Brimhall is also ostensibly directed to an intravenous catheter introducer assembly, with a catheter assembly and needle assembly, and a needle protector (Examiner asserts that needle shield 40 is such a protector and, for sake of argument, that will be accepted here without waiver of right to argue otherwise should that be necessary) that includes either a rigid spring gate 50, a leaf spring 60, or a tube 70 that cooperates with what Examiner considers to be a groove on the needle to hold the needle when it has been withdrawn. The leaf spring 60 has legs 63/64 that extend generally parallel to the axis of the needle, with leg 64 being urged against the needle surface to fall into the groove when the needle is withdrawn. Tube 70 has inwardly directed tabs 71 that also extend generally parallel to the needle axis and flex into the groove upon withdrawal of the needle.

In the parent case, Examiner rejected the claims on the basis that Brimhall's tube 70 and tabs 71 provided the inwardly directed flange. In other words, what Examiner now says is a clip/resilient leg was previously held to be an inwardly directed flange. Official Action mailed July 14, 2003, at 4-5. Examiner now tries to rely on that same structure as the claimed clip and resilient leg. The Office is precluded from taking the position that the same structure can be both an inwardly directed flange and a clip/resilient leg when Examiner has already held that the two are patentably distinct. Indeed, Examiner's assertion that tube 70 is a "clip" is simply untenable. Examiner provides no basis in fact to assert that a tube is a clip, as that term is plainly understood in the art. Hence, the rejections based on the tube 70 embodiment fail outright for all the reasons set out above.

Moreover, in the previous Official Action in this case, Examiner apparently recognized that neither the leaf spring 60 nor the tube 70 provided the claimed clip/resilient leg. Instead, in the previous Official Action, Examiner relied on the spring gate embodiment of Brimhall. Applicants responded by pointing out that the spring gate clearly lacked a resilient leg. Examiner now responds with the leaf spring and tube embodiments (at least the latter already having been held by the Examiner to be patentably distinct from a clip/resilient leg species). Leaving aside the fundamental unfairness in such an approach, it is respectfully submitted that Examiner has failed to establish that Brimhall anticipates the claimed invention.

As mentioned, tube 70 is not fairly considered to be a clip, which leaves only the leaf spring 60 embodiment to address in detail.[2]

Each of rejected claims 1-6, 8-10 and 12 (as well as new dependent claims 13-20) call for the "catheter hub having a retainer for keeping said protector within said catheter hub . . . . ." There is no such retainer in Brimhall, even assuming that the needle shield 40 is the "protector" of Brimhall. Examiner references col. 5, lines 8-13 of Brimhall for the alleged teaching of a retainer. But even a cursory review of that text shows that it is not referring to a "catheter hub having a retainer", but is instead referring to the needle shield fingers 47 and projections 48, which grip about the outer periphery of the catheter hub. Merely because the needle shield allegedly has structure to hold the needle shield to the catheter hub does not mean the catheter hub has that structure. The catheter hub of Brimhall does not have the fingers and projections, as they are on the needle shield. If Examiner is to persist in the rejection, Examiner is asked to identify the structure that the catheter hub has that defines the retainer.

Still further, the retainer is to keep the protector "within" the catheter hub. Examiner is requested to identify where Brimhall discloses that the needle shield is "within" the catheter hub. To the extent that "within" is satisfied by only a portion of the needle shield being in the catheter hub, Applicants have added new claims 15-17 which call for either the hollow member or clip to be completely within the catheter hub (claims 15 and 17, respectively) or for the resilient leg to be within the catheter hub (claim 16) even if that covers only partially within, as Examiner must be viewing the term in order to make the rejections. Brimhall fails on all three accounts. The needle shield 40 is clearly not completely within the catheter hub and no portion of leaf spring 60 is within the catheter hub under any construction of "within.". Hence, irrespective of how Examiner might choose to construe claim 1 and Brimhall, clearly at least newly added claims 15-17 are patentable thereover in their own right. Indeed, several other of the dependent claims are submitted to be patentable in their own right in any event.

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[2] While not believed necessary, and without making any concession or admission, Applicant will endeavor to discuss the tube 70 embodiment herein for sake of completeness.

For example, in addition to claims 15-17 discussed above, Brimhall does not disclose the subject matter of at least claims 4, 10, 13, 14, 18-20 as well. Original claim 4 recites that the needle and the hollow member have non-circular cross-sections, whereas claim 8 recites that the needle is cylindrical. Brimhall discloses only one needle, and so it is not seen how it can be both cylindrical and non-circular at the same time. Indeed, the non-circular aspects are so that the hollow member and needle cannot rotate relative to each other. Examiner is requested to identify any structure of Brimhall that aids in avoiding such rotation, much less a shape of the needle and hollow member in order to support the rejection of claim 4. Applicants pointed out this deficiency in response to the prior Official Action, but Examiner did not address the point in the present Official Action.

Similarly, original claim 10, and new claim 20, each recite that the clip is a wireform. A leaf spring is not a wireform (nor is a tube, for that matter). Nor has Examiner explained how the term could be construed to reach anything in Brimhall.

New claim 13 calls for the protector hollow member to have a substantially constant inner cross-section between the distal and proximal ends. By contrast, the needle shield of Brimhall cannot have such a feature. For the leaf spring, what Examiner asserts is the hollow member has an area that is much larger than the rest of the hollow member, in order to accommodate the leaf spring. Similarly, for the tube, the needle shield is stepped so that the tube 70 can be held therein. As the Brimhall needle shield "hollow member" is not of a substantially constant inner cross-section, Brimhall cannot anticipate the invention of claim 13. Further, the change in inner cross-section of Brimhall appears to be a requirement for proper operation thereof, such that it is submitted that it would not have been obvious to modify Brimhall to make the needle shield interior cross-section substantially constant.

New claim 14 adds that the resilient leg extends generally along a plane that is generally perpendicular to the needle axis, as seen especially in Figure 10. By contrast, the "legs" of Brimhall extend generally parallel to the needle axis, which is about 90° different from what is claimed. Applicants submit that there is no teaching or suggestion in Brimhall to make such a drastic change. New claim 18 depends from original claim 3 and calls for the resilient legs of the U-shaped clip to extend into the hollow member with the needle between the legs. Examiner has not shown how he is construing either leaf spring 60 or tube 70 to be U-shaped for purposes of claim 3, but is asked to do so if a rejection thereof is to be maintained. In any event, it is submitted that tube 70 is neither a clip nor U-shaped anyway, and assuming for sake of argument that Examiner asserts that leaf spring 60 is U-shaped, there is clearly nothing that could be considered as two legs with the needle therebetween.

Finally, new claim 19 specifies that a portion of the clip is outside the hollow member as shown, for example, in Figure 10 of the present application. That is clearly not the case with either leaf spring 60 or tube 70 of Brimhall.

In view of the above, it is respectfully submitted that all of the pending claims distinguish over Brimhall and are allowable over the art.

Conclusion

In view of the above, Applicants submit that the rejections are in error, no new rejections should be made, and all claims are now in condition for allowance. Accordingly, a Formal Notice of Allowance is respectfully solicited.

Applicants have undertaken to respond to all issues raised in the Official Action. In the event that any issues remain outstanding, Examiner is invited to contact the undersigned to expedite prosecution of this application.

No fee is believed due with this paper. If any fee is due, the Commissioner is authorized to charge any such fee or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,
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